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#13

Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 15-22  
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 4,696,949 was filed on July 23, 1997, under 35 U.S.C. § 156. U.S. Patent No. 4,696,949 issued on September 29, 1987 from an application that was filed on May 25, 1983. Accordingly, the original expiration date of the patent is September 29, 2004.

The assistance of your Office is requested in confirming that the product identified in the application, FARESTON® (toremifene citrate), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Telephone inquiries regarding this communication should be directed to the undersigned at (703) 306-3159.

Karin Tyson  
Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Ronald J. Kubovcik  
Kubovcik & Kubovcik  
900 17th St. NW  
Suite 990  
Washington DC 20006